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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,146	02/11/2002	Stephen M. Testa	GERC 117991	7913

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	**PAPER NUMBER**
1634	8

DATE MAILED: 03/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/936,146	Testa
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 11, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Feb 11, 2002* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-2, 4, 7-9, 11, 13-15, 17, and 20-21 are rejected under 35 U.S.C. 103(a) over Leibowitz et al. (U.S. Patent 5,849,484) (December 15, 1998) in view of McSwiggen (U.S. Patent 5,525,468) (June 11, 1996).

Leibowitz et al teach an inhibitor of a Group I intron self-splicing reaction comprising a compound that binds to a 5' internal guide sequence of a precursor RNA containing a Group I intron, or to a portion thereof, wherein the compound is capable of binding with the 5' internal

guide sequence of the precursor RNA and of being trans-spliced to the 3'-exon of the precursor RNA (Abstract, Figures 13 A to 13D, 14 A-B, and Figure 1).

Leibowitz et al teach a method for inhibiting the growth of an organism by Group I intron self-splicing reaction comprising a compound that binds to a 5' internal guide sequence of a precursor RNA containing a Group I intron, or to a portion thereof, wherein the compound is capable of binding with the 5' internal guide sequence of the precursor RNA and of being trans-spliced to the 3'-exon of the precursor RNA (Abstract, Figures 13 A to 13D, 14 A-B, and Figure 1 and Column 12, line 10 to column 16, line 27).

Leibowitz et al teach a method for designing an inhibitor of Group I intron splicing (Column 8, lines 15-21).

Leibowitz et al teach the precursor RNA is ribosomal RNA from Pneumocystis carinii (Abstract and claim 1 and Figures 13 A to 13D, 14 A-B).

Leibowitz et al teach an inhibitor together with pharmaceutically acceptable carrier (Figures 13 A to 13D, 14 A-B).

Leibowitz et al do not teach an oligonucleotide that binds to a 5' internal guide sequence to a precursor RNA containing a Group I intron, or to a portion thereof, wherein the compound is capable of binding with the 5' internal guide sequence of the precursor RNA and of being trans-spliced to the 3-exon of the precursor RNA.

McSwiggen teaches an oligonucleotide that binds to a 5' internal guide sequence to a precursor RNA containing a Group I intron, or to a portion thereof, wherein the compound is

capable of binding with the 5' internal guide sequence of the precursor RNA and of being trans-spliced to the 3-exon of the precursor RNA including SEQ ID NO:2 (Figure 7 and Column 7, lines 40-45).

McSwiggen also teaches the method, wherein the oligonucleotide comprises deoxynucleotides, ribonucleotides, or a combination thereof, and the oligonucleotide comprises a 3' terminal ribonucleoside (Tables 1 and 2 and Figures 1,7, and 8).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the substrate-binding domain of ribozymes of McSwiggen which are resistant to self-splicing in the study of inhibitors of Group I intron self-splicing reaction of Leibowitz et al, since Leibowitz et al states, "Since various compounds can specifically inhibit the splicing of Group I introns in vitro, Group I intron splicing may provide a specific target for development of new therapeutic agents against P. Carinii (Column 8, lines 15-21). An ordinary artisan would have been motivated to substitute and combine the substrate-binding domain of ribozymes of McSwiggen which are resistant to self-splicing in the study of inhibitors of Group I intron self-splicing reaction of Leibowitz et al. in order to achieve the express advantages, as noted by Leibowitz et al., of a method which provides a specific target for development of new therapeutic agents against P. Carinii.

3. Claims 3, 5, 10, 12, 16, 18, and 22 are rejected under 35 U.S.C. 103(a) over Leibowitz et al. (U.S. Patent 5,849,484) (December 15, 1998) in view of McSwiggen (U.S. Patent 5,525,468) (June 11, 1996) further in view of Letsinger et al. (U.S. Patent 5,648,480) (July 15, 1997).

Leibowitz et al. in view of McSwiggen teach the inhibitor and methods of claims 1-2, 4, 6-9, 11, 13-15, 17, and 19-21 as described above.

Leibowitz et al in view of McSwiggen do not teach an oligonucleotide SEQ ID NO: 1 having a 3'--->P5' phosphoramidate linkage.

Letsinger et al. teach an oligonucleotide SEQ ID NO: 1 having a 3'--->P5' phosphoramidate linkage (Abstract, Tables 1 and 2, and Column 13 to Column 16, and SEQ ID NO: 3) .

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the SEQ ID NO: 1 and the process for making oligonucleotides linkage of Letsinger et al in the study of inhibitors of Group I intron self-splicing reaction of Leibowitz et al. in view of McSwiggen, since Leibowitz et al states, "Since various compounds can specifically inhibit the splicing of Group I introns in vitro, Group I intron splicing may provide a specific target for development of new therapeutic agents against P. Carinii (Column 8, lines 15-21). Moreover Letsinger et al provides further motivation as Letsinger et al states, "The present invention relates to oligonucleotides having use in diagnostics and antisense research and therapeutics (Column 1, lines 16-17)". An ordinary artisan would have been motivated to substitute and combine the SEQ ID NO: 1 and the process for making

oligonucleotides linkage of Letsinger et al in the study of inhibitors of Group I intron self-splicing reaction of Leibowitz et al. in view of McSwiggen in order to achieve the express advantages, as noted by Leibowitz et al., of a method which provides a specific target for development of new therapeutic agents against P. Carinii, and also to achieve the express advantages, as noted by Letsinger et al., of a method which provides oligonucleotides having use in diagnostics and antisense research and therapeutics.

4. Claims 6 and 19 are rejected under 35 U.S.C. 103(a) over Leibowitz et al. (U.S. Patent 5,849,484) (December 15, 1998) in view of Sandhu et al. (U.S. Patent 6,180,339 B1) (January 30, 2001).

Leibowitz et al. teach the inhibitor and methods of claims 1-2, 4, 7-9, 11, 13-15, 17, and 20-21 as described above.

Leibowitz et al. do not teach a precursor ribosomal RNA from *Candida albicans*.

Sandhu et al. teach a precursor ribosomal RNA from *Candida albicans* (Abstract, Table 4, and Column 3, lines 8-21, and Column 4, lines 19-67) .

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the precursor ribosomal RNA from *Candida albicans* of Sandhu et al. in the study of inhibitors of Group I intron self-splicing reaction of Leibowitz et al., since Sandhu et al. states, "*Candida albicans* is one of the most common causes of fungal infections in humans (Column 3, lines 8-9). Moreover, Sandhu et al provides further motivation as Sandhu et al. states, "This identifies only *Candida albicans* and detects other

Candida species without identifying individual organisms (Column 4, lines 37-39)". An ordinary artisan would have been motivated to substitute and combine the precursor ribosomal RNA from *Candida albicans* of Sandhu et al. in the study of inhibitors of Group I intron self-splicing reaction of Leibowitz et al. in order to achieve the express advantages, as noted by Sandhu et al., of nucleotides which identifies only *Candida albicans,* which is one of the most common causes of fungal infections in humans and detects other Candida species without identifying individual organisms.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

March 19, 2003

ARUN K. CHAKRABARTI
PATENT EXAMINER